APR 1 8 2001

K 010676

**Sterling Medivations, Inc.**
**180 Ferndale Road South**
**Wayzata, Minnesota 55391**
**952-473-7971 (voice)**
**952473-4758 (fax)**

**510(k) SUMMARY**

**Date Submitted:** March 5, 2001

**Submitter:** Sterling Medivations, Inc. 180 Ferndale Road South, Wayzata, MN 55391 Company Phone 952-473-7971, Company fax 952-473-4758

**Contact:** Joel Douglas, Chief Technology Officer
Sterling Medivations, Inc.
Applicant Phone 650-949-0470, Applicant Fax 650-949-0342

**Trade Name of Device:** Simplicity™ Winged QD Infusion Set for use with the MiniMed™ infusion pumps and MiniMed medication reservoirs (model MMT-103) FDA 510(k) K991936.

**Common Name of Device:** Intravascular administration set.

**Classification Name:** Percutaneous intravascular catheter.

**Predicate Device:** The predicate device for Sterling's Simplicity™ Winged QD Infusion set is the MiniMed Polyfin™ QR Infusion Set sold by MiniMed FDA 510(k) K964455 and the Sterling Medivations Simplicity with Wings Infusion Set FDA 510(k) K003283.

**Description of the New Device:** Sterling Medivations, Inc.'s ("SMI") Simplicity ™ Winged QD Infusion Set is designed for use by people with diabetes to provide a means to infuse insulin subcutaneously when the device is attached to a MiniMed medication reservoir (model MMT-103) or equivalent means.

The Simplicity ™ Winged QD Infusion Set proposed for commercial distribution is similar in all significant respects to the existing MiniMed Polyfin™ QR Infusion Set and it has the same intended use.

The device consists of four main parts: (1) an infusion catheter made from AISI 302 stainless steel, (2) an infusion hub that provides the patient an adhesive pad to attach the indwelling catheter to the body, (3) a connection tube, (4) a female Luer pump connector and (5) a Quick Disconnect Fitting joining the connecting tube.

The Simplicity Winged QD Infusion Set is an infusion administration set, connecting to a medicine reservoir syringe (such as the MiniMed reservoir, model 103, that is placed in an external infusion pump such as the insulin pump and inserted in the subcutaneous tissue of a patient. The Sterling Medivations Simplicity Winged QD Infusion Set may be used with any infusion pump reservoir that utilizes a standard Luer connector.

The administration set attaches to the reservoir/syringe by means of a female Luer connector, and subcutaneously to the patient through an indwelling catheter made from AISI 302 stainless steel. The connecting tubing is made from a polyethylene tube.

The 27 gauge-indwelling catheter made from AISI 304 stainless steel is introduced into the subcutaneous tissue the patient. The gauge-indwelling catheter made from AISI 304 stainless steel is connected to the connecting tubing in an infusion hub at the distal end. The connector tubing proximal end is attached to a female Luer connector for attachment to the medicine reservoir.

**Intended Use of the New Device**: The intended use of the Simplicity Winged QD Infusion Set is to provide a means to infuse insulin subcutaneously when the device is attached to a MiniMed medication reservoir (model MMT-103). The



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Simplicity Winged QD Infusion Set is substantially equivalent to the MiniMed Polyfin QR Insertion Set sold by MiniMed FDA 510(k) K964455 and the Sterling Medivations Simplicity with Wings Infusion Set FDA 510(k) K003283.

**Comparisons of the Technological Features of the New Device and Predicate Device:**

The Simplicity Winged QD Infusion Set proposed for commercial distribution is similar in all significant respects to the existing MiniMed Polyfin QR Infusion Set 510(k) K964455.

The materials and manufacturing processes are substantially equivalent, the labeling is substantially equivalent and it has the same intended use as the MiniMed Polyfin QR Insertion Set sold by MiniMed FDA 510(k) K964455 and the Sterling Medivations Simplicity with Wings Infusion Set FDA 510(k) K003283.

The differences that exist between the new and predicate device are as follows:

1. The new device has a connecting tube of Polyethylene and the predicate device has a connecting tube of co-extruded connecting tube Polyethylene ID and PVC OD.
2. The new device has a sliding disconnect needle that eliminates the need to carry the protective cap used with the predicate device and thereby makes it easier to disconnect

**Performance Data Supporting Substantial Equivalence**: To provide substantial equivalence both Simplicity Winged QD Infusion Set and MiniMed Polyfin QR Infusion Set K964455 meet the catheter requirements of:

CDRH 21 C.F.R. section 880.54400 Intravascular administration set,
ISO 10555 Sterile, single use intravascular catheters (Part 1: General Requirements), and
ISO 10555 Sterile, single use intravascular catheters (Part 5: peripheral catheters).,
ISO 9626 Stainless steel needle tubing for the manufacture of medical devices,
ISO 11135: 1994 Medical devices – Validation and routine control of ethylene oxide sterilization,
ISO 11138-2:1994 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization.
ISO 594-1: 1986 Conical fittings with a 6% )Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements,
ISO 594-2: 1998 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings,
ISO 11607: 1997 Packaging for terminally sterilized medical devices,
ISO 8537: 1991 Sterile single use syringes, with or without needle for insulin,
ISO 11135: 1994 Medical devices – Validation and routine control of ethylene oxide sterilization,
ISO 11138-2: 1994 Sterilization of health care products – Biological indicators – Part 2:Biological indicators for ethylene oxide sterilization.

FDA Guidelines on validation of the Limulus Amebocyte Lysate (LAL) Test as an end-product endotoxin test for human and animal parenteral drugs, biological products, and medical devices. ODE Blue Book Memorandum #K90-1.

The design process adhered to is the Center of Devices and Radiological Health. DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS. This Guidance relates to FDA 21 CGR 820.30 and Sub-clause 4.4 of ISO 9001. This is substantially equivalent to the predicate device.

Signed

Joel S. Douglas
Chief Technology Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2001

Mr. Joel Douglas
Chief Technology Officer
Sterling Medivations, Incorporated
180 Ferndale Road South
Wayzata, Minnesota 55391

Re: K010676
Trade/Device Name: Simplicity Winged QD Infusion Set
Regulation Number: 880.5440
Regulatory Class: II
Product Code: FPA
Dated: March 5, 2001
Received: March 6, 2001

Dear Mr. Douglas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010676

510(k) Number (if known):

Device Name: Simplicity Winged QD Infusion Set

Indications For Use:

The intended use of the Simplicity Winged QD Infusion Set is to provide a means to infuse insulin subcutaneously when the device is attached to a MiniMed medication reservoir (model MMT-103).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Tatiana Cascante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010676